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BPHARM
(SEM VI) THEORY EXAMINATION 2025-26
QUALITY ASSURANCE- THEORY

TIME: 3 HRS

M.MARKS: 75

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt all questions in brief. 10 x 2 = 20

a.	Write the basic need of quality control.
b.	Write the role of maintenance department in a pharma industry.
c.	Define quality audit.
d.	Write the purpose of distribution records.
e.	Write the basic purpose of material management.
f.	Define Good warehouse practice.
g.	Write the salient features of ISO9000.
h.	Write the principle of GMP.
i.	Define environment control.
j.	Write a note on sanitation.

SECTION B

2. Attempt any two parts of the following: 2 x 10 = 20

a.	Write the principle and procedure of NABL accreditation.
b.	Write the quality control tests for containers
c.	Describe the basic components of a batch formula record.

SECTION C

3. Attempt any five parts of the following: 7 x 5 = 35

a.	Write the ICH stability testing guidelines.
b.	Classify industrial waste; explain the waste disposal system.
c.	Write the disqualification of testing facilities.
d.	Write a brief overview of QSEM.
e.	Write the design construction and plant layout.
f.	Discuss the personnel and facilities for GLP.
g.	Why we prepare SOP? Write the SOP of one laboratory instrument.